and the inner tubular member [of the tubular member such that a liquid may be applied within the lumen of the tubular member]; and,

at least one <u>vent</u> aperture for purging air from said lumen of the catheter body, said aperture extending radially through said <u>outer</u> wall of the <u>outer</u> tubular member at a [point] location proximal [to] of the proximal portion of the inflatable balloon.

14. (Amended) A balloon catheter as defined in Claim 12, wherein said liquid applied within the lumen of the <u>outer</u> tubular member exerts a fluid pressure between about 20 psi and 45 psi and thereby causes air to pass through the <u>vent</u> aperture.

Please cancel claim 17, subject to the possible filing a divisional application.

## <u>REMARKS</u>

Applicant notes with appreciation the courteous interview granted to counsel for applicant on November 21, 2002. Pursuant to the interview and in order to more clearly distinguish applicant's invention over the prior art, claims 1, 4, 6, 9, 11 and 14 have been amended. Reconsideration and allowance of the application as amended are respectfully requested.

The present invention concerns a novel balloon catheter comprising a catheter body which comprises an outer tubular member having an outer tubular wall and having a lumen extending throughout the length of the outer tubular member. The catheter body also includes an inner tubular member having a lumen extending therethrough. An inflatable balloon is bonded to the outer tubular member. A coupling member is provided having a lumen extending therethrough, with a coupling member being mounted on the proximal end of the outer tubular member and the lumen of the coupling

member communicating with the lumen between the outer tubular member and the inner tubular member.

A syringe is coupled to the coupling member for applying a liquid within the lumen of the outer tubular member. At least one vent aperture is provided for purging air from the lumen of the catheter body. The aperture extends radially through the outer tubular wall of the outer tubular member at a location proximal of the proximal portion of the inflatable balloon.

During the interview, it was pointed out how the Burns et al. patent did not disclose applicant's invention as claimed. Burns et al. has a vent lumen 43 which requires an additional tube 42, located within tube 24, which is located within tube 29. This additional tube requires another layer of material, which makes the catheter less flexible. Further, tube 42 can serve to interfere with the guidewire, the venting path is tortious, requiring pathway through 46, then 43, then out of 47. At the interview, the Examiners agreed that the proposed amendment overcame the Burns et al. patent.

During the interview, the Examiners brought to counsel's attention Zadno-Azizi U.S. Patent No. 6,231,588 and Euteneuer et al. U.S. Patent No. 4,943,278. Both of these patents have been studied carefully and the claims have been amended to clearly distinguish applicant's invention from the disclosures of these two patents.

With respect to Zadno-Azizi, that patent is not pertinent because the invention disclose therein is an angioplasty catheter which has an aspiration hole that is used after the angioplasty procedure. The aspiration hole is used to retrieve the angioplasty particles, not to purge the balloon. In sharp contrast to applicant's invention, instead of injecting a liquid into the catheter as with applicant's invention, in Zadno-Azizi a syringe

would be used to draw a vacuum after the angioplasty, to aspirate the system. Clearly opening 384 of Zadno-Azizi is an aspiration port, not a vent opening as in applicant's claimed invention.

Applicant's claims also very clearly distinguish applicant's invention over the Euteneuer et al. patent. In Euteneuer et al., catheter 52 is a metal hypotube, and there is a metal vent tube 76. Metal tube 76 has an entrance 84 through which the air flows back through the tube to vent opening 86. Vent opening 86 is defined by the inner metal tube 76. Among other things, Euteneuer does not disclose or suggest a catheter comprising an outer tubular member defining a lumen and an inner tubular member defining a lumen, with the inner tubular member being disposed through the lumen of the outer tubular member to form a lumen between the outer tubular member and the inner tubular member, together with a coupling member mounted on the proximal end of the outer tubular member with the lumen of the coupling member communicating with the lumen between the outer tubular member. In fact, Euteneuer et al. teaches away from having a coupling member mounted on the proximal end of the outer tubular member which communicates with a lumen between the outer tubular member and the inner tubular member mounted on the

Applicant's invention is a significant improvement over the prior art patents because applicant's invention is relatively simple in construction, relatively easy to manufacture, and provides means for purging air from the catheter with a liquid that is novel and highly efficient.

In view of the foregoing amendments and remarks, it is submitted that the present invention is in condition for allowance and an early notice of allowance is respectfully requested.

Respectfully submitted, SEYFARTH SHAW

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## **CERTIFICATE OF MAILING**

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to: Honorable Commissioner of Patents and Trademarks, Washington, D.C. 20231 on November 26, 2002.

Registered Attorney for Applicant

Date: November 26, 2002

Boris Shkolnik

Serial No.: 09/578,317 Filed: May 25, 2000

For: INFLATABLE BALLOON CATHETER WITH PURGE MECHANISM AND METHOD

## **CLEAN COPIES OF AMENDED CLAIMS**

(Amended) A balloon catheter comprising:

a catheter body comprising an outer tubular member having an outer tubular wall and having a lumen extending throughout the length of the outer tubular member, said outer tubular member further having a proximal end and a distal end;

said catheter body further including an inner tubular member having a proximal end, a distal end, and a lumen extending therethrough, said inner tubular member being disposed through said lumen of the outer tubular member to form a lumen between the outer tubular member and the inner tubular member;

an inflatable balloon having a main body portion, a proximal portion, and a distal portion, said proximal portion and said distal portion extending from said main body portion, said distal portion of the balloon being bonded to the outer tubular member near the distal end of the outer tubular member and said proximal portion of the balloon being bonded to the outer tubular member proximal to the distal portion of the balloon, said inflatable balloon being formed from a gas-permeable material;

a coupling member having a lumen extending therethrough, said coupling member being mounted on the proximal end of the outer tubular member and the lumen of the coupling member communicating with the lumen between the outer tubular member and the inner tubular member;

a syringe coupled to said coupling member for applying a liquid within the lumen of the outer tubular member; and,

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at least one vent aperture for purging air from said lumen of the catheter body, said aperture extending radially through said outer tubular wall of the outer tubular member at a location proximal of the proximal portion of the inflatable balloon.

4. (Amended) A balloon catheter as defined in Claim 2, wherein said vent aperture is of a size to permit the flow of air through the aperture while restricting the flow of liquid through the aperture.

6. (Amended) A balloon catheter comprising:

and having a lumen extending throughout the length of the outer tubular member, said outer tubular member further having a proximal end and a distal end;

said catheter body further including an inner tubular member having a proximal end, a distal end, and a lumen extending therethrough, said inner tubular member being disposed coaxially through said lumen of the outer tubular member to form a lumen between the outer tubular member and the inner tubular member;

an inflatable balloon having a main body portion, a proximal portion, and a distal portion, said proximal portion and said distal portion extending from said main body portion, said proximal portion of the balloon being bonded to the distal end of the outer tubular member and the distal portion of the balloon being bonded to the distal end of the inner tubular member, said inflatable balloon being formed from a gas-permeable material;

a coupling member having a lumen extending therethrough, said coupling member being mounted on the proximal end of the outer tubular member and the lumen

of the coupling member communicating with the lumen between the outer tubular member and the inner tubular member;

a syringe coupled to said coupling member for applying a liquid within the lumen of the outer tubular member; and, at least one vent aperture for purging air from said lumen of the catheter body, said aperture extending radially through said outer tubular wall of the outer tubular member at a location proximal of the proximal end of the inflatable balloon.

9. (Amended) A balloon catheter as defined in Claim 7, wherein said vent aperture is of a size to permit the flow of air through the aperture while restricting the flow of a liquid through the aperture.

11. (Amended) A balloon catheter comprising:

a catheter body comprising an outer tubular member having an outer tubular wall and having a lumen extending throughout the length of the outer tubular member, said outer tubular member further having a proximal end and a distal end;

said catheter body further including an inner tubular member having a proximal end, a distal end, and a lumen extending therethrough, said inner tubular member being disposed through said lumen of the outer tubular member to form a lumen between the outer tubular member and the inner tubular member;

an inflatable balloon having a main body portion, a proximal portion, and a distal portion, said proximal portion and said distal portion extending from said main body portion, said distal portion of the balloon being bonded to the outer tubular member near the distal end of the outer tubular member and said proximal portion of the balloon being bonded to the outer tubular member proximal to the distal portion of the balloon;

a coupling member having a lumen extending therethrough, said coupling member being mounted on the proximal end of the outer tubular member and the lumen of the coupling lumen communicating with the lumen between the outer tubular member and the inner tubular member; and,

at least one vent aperture for purging air from said lumen of the catheter body, said aperture extending radially through said outer wall of the outer tubular member at a location proximal of the proximal portion of the inflatable balloon.

14. (Amended) A balloon catheter as defined in Claim 12, wherein said liquid applied within the lumen of the outer tubular member exerts a fluid pressure between about 20 psi and 45 psi and thereby causes air to pass through the vent aperture.